

Notice of Allowability

Application No.

10/552,676

Examiner

Michael P. Barker

Applicant(s)

SOUVIE ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/7/05.
2. ☒ The allowed claim(s) is/are 5-8.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 10/7/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Claims 5-10 are pending in this Application and subject to a Restriction Requirement.

Claims 5-8 are in condition for allowance. After election of Group I, **Claims 5-8**, Group II,

Claims 9-10, is canceled via Examiner's Amendment, *infra*.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 7, 2005 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS was considered by the Examiner. Please refer to Applicant's copy of PTO-1449, submitted herewith.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 5-10 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision set forth in PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 further states unity of invention as referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Special technical

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features, as defined in PCT Annex B, Part 1(b), include those technical features *which define a contribution over the prior art*.

PCT Annex B, Part 1(e) provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,...

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

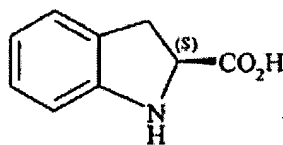
Group I: Claims 5-8 are drawn to a process of preparing (2S)-indoline-2-carboxylic acid.

Group II: Claims 9-10 are drawn to a process of preparing perindopril, using (2S)-indoline-2-carboxylic acid.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Applicant may choose to elect a single invention, and Examiner will endeavor to search that invention. The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 CFR 1.475(a):

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Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features. . .those technical features *that define a contribution* which each of the claimed inventions, considered as a whole, makes *over the prior art*. [emphasis added].



The structural moiety common to **Groups I-II** is . This technical feature cannot be considered a *special* technical feature, because it fails to make a contribution over the prior art, *see*: US Patent No. 4,914,214. The '214 patent discloses the technical feature described above, namely (2S)-indoline-2-carboxylic acid.

Even if unity of invention cannot be said to be lacking based on the rationale presented above, i.e. there is no *special* technical feature, Group I is drawn to a process of preparing (2S)-indoline-2-carboxylic acid, whereas Group II is drawn to a process of preparing perindopril. Unity of invention cannot be said to exist where there are two claimed processes resulting in two entirely different end-products. Therefore, **Claims 5-10** are not so linked as to form a single general inventive concept; accordingly, there is lack of unity of invention.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to one invention. Since the claims lack unity of invention, Applicant is required to elect a single invention. If the elected invention is found to be free of the prior art, the restricted claims will be examined along with the elected invention *so long as they are commensurate in scope therewith*. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

A telephonic Restriction Requirement was presented to Michele Cudahy on November 17, 2006, which resulted in the election without traverse of Group I, **Claims 5-8**.

Claims 9-10 are not commensurate in scope with **Claims 5-8**. Therefore, Group II, **Claims 9-10**, is not rejoined. As A telephone call was made to *** on *** to request an oral election to the above restriction requirement, but did not result in an election being made.

This Application is in condition for allowance except for the presence of **Claims 9-10** directed to a process of preparing perindopril. This invention is drawn to nonelected subject matter. Accordingly, **Claims 9-10** are cancelled via Examiner's Amendment.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Cancel **Claims 9 and 10**.

Reasons for Allowance

Applicant's invention is drawn to a process of preparing (2S)-indoline-2-carboxylic acid by means of a resolution reaction between (2S)-indoline-2-carboxylic acid and a chiral amine, followed by recirculation of the mother liquor, resulting in a greater percentage of the (2S) enantiomer of indoline-2-carboxylic acid than is disclosed in the prior art.

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The closest prior art, U.S. Patent No. 4,914,214, issued April 3, 1990. The '214 patent discloses a process of preparing (2*S*)-indoline-2-carboxylic acid resulting in a 35% yield of (2*S*)-indoline-2-carboxylic acid. The claimed invention's novelty involves resolving the racemic indoline-2-carboxylic acid to give the (2*S*) enantiomer, while recirculating the mother liquor, a racemic mixture, the majority of which is the (2*R*) enantiomer. The '214 patent does not teach nor suggest the conditions under which racemization and recirculation is carried out in the instant Application. Therefore, **Claims 5-8** are ALLOWED.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.



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